KEY FINDINGS

Analysis of California Assembly Bill 2467 Menopause

Summary to the 2023-2024 California State Legislature, April 16, 2024

CHBRP

Summary

AB 2467 would require coverage for treatment of menopause symptoms, including but not limited one particular drug and multiple bill-identified therapeutic categories of drugs.

Benefit Coverage: At baseline, 13,162,000 enrollees have an outpatient pharmacy benefit regulated by the Department of Managed Health Care (DMHC) or California Department of Insurance (CDI). Among them, at baseline, 7% have coverage for fezolinetant and 15% have coverage for ospemifene. For other drugs and categories, baseline coverage ranges from 92% to 100%. Postmandate, coverage for these drugs and categories would be 100%.

Medical Effectiveness: There is a *preponderance of evidence* for the effectiveness of fezolinetant as well as ospemifene, and *limited evidence* for the effectiveness of high-dose vaginal estrogen. More broadly, commonly referenced clinical guidelines indicate that systemic hormonal therapy and nonhormonal therapy can be effective.

Cost and Health Impact: Utilization of other drugs is expected to increase in proportion to the increase in benefit coverage, so greatest for fezolinetant as well as ospemifene. This would result in an increase of total net annual expenditures for enrollees with DMHC-regulated plans and CDI-regulated policies of $3,993,000 (0.0025%). Within the first year postmandate, CHBRP finds that AB 2467 would improve the health of the women receiving the 15,880 (30-day) prescriptions under new coverage (which might translate to ~1,323 women, assuming each received one prescription for 12 consecutive months).

Context

Menopause is part of the normal aging process. Perimenopause is the period of 1 to 3 years when menstruation becomes irregular, and menopause is when menstruation has ceased for 12 consecutive months. This transition to a new stage of life (rather than a condition or disease) is experienced by every woman and most often occurs naturally between ages 45 and 55 years but may occur between ages 40 and 64 years (median age 51 years). During the menopause transition, the ovaries produce less estrogen and progesterone as they stop releasing eggs. Menopause can also begin with surgical removal of the ovaries. The decrease in the hormonal levels may lead to moderate-to-severe symptoms prompting requests for treatment.

Bill Summary

AB 2467 would require coverage for treatment of menopause symptoms, including but not limited to one particular drug and multiple bill-identified therapeutic categories of drugs.

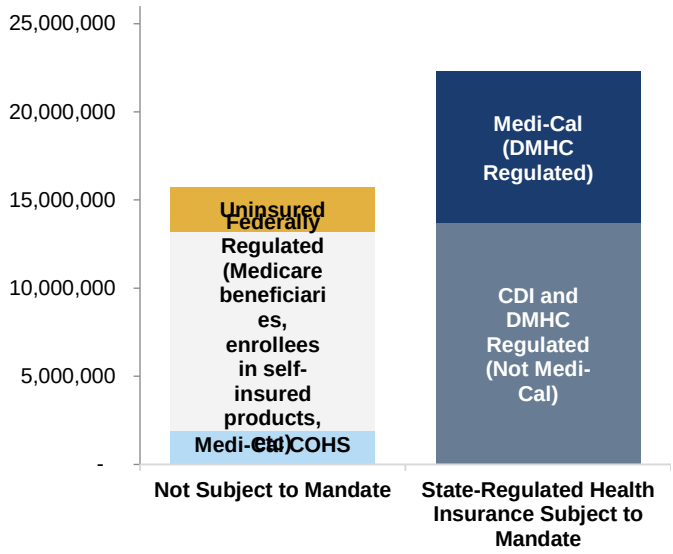
Analytic Approach

Almost all (96.2%) commercial/CalPERS enrollees have a pharmacy benefit regulated by DMHC or CDI that covers both generic and brand-name outpatient prescription drugs.[1] CHBRP has assumed that AB 2467 would not require creation of a pharmacy benefit and so baseline benefit coverage for enrollees would be compliant so long as they (1) are without a pharmacy benefit or (2) their pharmacy benefit is not regulated by DMHC or CDI. The latter group includes all Medi-Cal beneficiaries enrolled in DMHC-regulated plans, as their pharmacy benefit is through the Medi-Cal program (not the DMHC-regulated plan). So, although all 22.3 million enrollees in plans and policies regulated by DMHC or CDI have health insurance that would be subject to AB 2467 (see Figure A), impacts would only among the 13.2

[1] For more detail, see CHBRP's resource *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at www.chbrp.org/other-publications/resources.

million who currently have a pharmacy benefit regulated by DMHC or CDI.

Figure A. 2025 Health Insurance in CA



Source: California Health Benefits Review Program, 2024.
Key: CDI = California Department of Insurance; COHS = County Organized Health System; DMHC = Department of Managed Health Care.

CHBRP has assumed that plans and policies with a pharmacy benefit regulated by DMHC or CDI would be compliant postmandate if at least one drug per therapeutic category is covered.

CHBRP has restricted utilization estimates to women aged 40 to 64. Older women are not included because the benefit coverage of Medicare beneficiaries would not be affected by AB 2467.

Medical Effectiveness

Commonly referenced guidelines indicate that hormone therapy remains the most effective treatment for vasomotor symptoms (VMS) and genitourinary syndrome of menopause (GSM), and has been shown to prevent bone loss and fractures. Hormone therapy risks depend on type, dose, duration of use, route of administration, timing of initiation, and whether a progestogen is used.

There is *clear and convincing evidence* that low-dose vaginal estrogen for the treatment of GSM is effective.

There is *limited evidence* that high-dose vaginal estrogen is effective at treating VMS (hot flashes).

There is *limited evidence* that compounded bioidentical hormones are effective treatment for menopause symptoms. Use of compounded bioidentical hormones is only recommended for patients with an allergy to an active pharmaceutical ingredient or inactive ingredient of a drug product approved by the FDA or documented requirement for a different dosage form than available. This is due to serious concerns about the safety, efficacy, and standardization of these drugs, which are not regulated by the FDA.

There is a *preponderance of evidence* that fezolinetant is effective for treatment of VMS.

There is a *preponderance of evidence* that ospemifene improved symptoms GSM.

Impacts

Benefit Coverage

At baseline, 13.2 million enrollees have an outpatient pharmacy benefit regulated by DMHC or CDI. Among the specific drugs that CHBRP identified as treatments for menopause symptoms, an estimated 7% of enrollees in DMHC-regulated plans and CDI-regulated policies have coverage for fezolinetant and 15% have coverage for ospemifene at baseline. For other drugs and categories, baseline coverage ranges from 92% to 100%, and would increase to or remain at 100% for all if AB 2467 were enacted.

Utilization

Because CHBRP is concerned with estimating the marginal impact of AB 2467, the utilization analyses focus on drugs and treatments for which enrollees in DMHC-regulated plans and CDI-regulated policies did not have 100% coverage at baseline. As current utilization for both is nearly entirely as a noncovered benefit, the increase in benefit coverage would be expected to increase utilization for fezolinetant (231%) and ospemifene 187%). Utilization of other drugs and treatments would be expected to increase in proportion to the increase in benefit coverage.

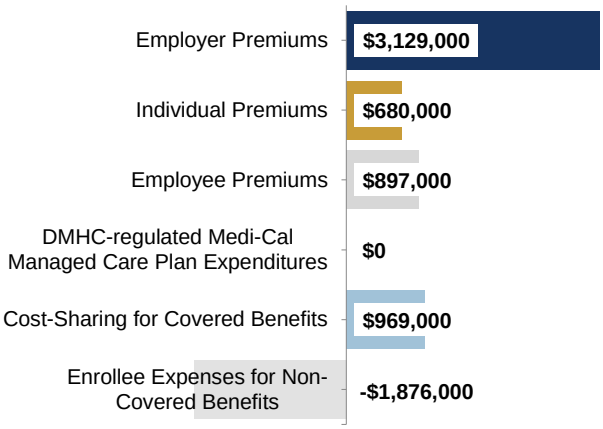
Expenditures

For enrollees in DMHC-regulated plans and CDI-regulated policies, AB 2467 would increase total premiums paid (by employers and enrollees) and cost sharing, though it would decrease expenses for

noncovered benefits (see Figure B). This would result in an increase of total net annual expenditures for enrollees with DMHC-regulated plans and CDI-regulated policies of $3,993,000 (0.0025%).

CHBRP projects no change to copayments or coinsurance rates but does project increases in utilization of some drugs and therefore an increase in enrollee cost sharing. Increases in utilization of covered benefits are a combination of reductions in utilization that was paid for out of pocket at baseline that would be covered under AB 2467 postmandate and new utilization due to increased take-up with increases in coverage.

Figure B. Expenditure Impacts of AB 2467



Source: California Health Benefits Review Program, 2024.
Key: DMHC = Department of Managed Health Care.

Public Health

Within the first year postmandate, CHBRP finds that AB 2467 would reduce or abate menopause symptoms for women receiving the additional 15,400 (30-day) prescriptions (which might translate to ~1,250 women, assuming each received one prescription for 12 consecutive months).

Long-Term Impacts

CHBRP does not anticipate any additional changes postmandate that are different from the new levels of coverage established under AB 2467. If a lower-cost drug option were to become available, DMHC-regulated plans and CDI-regulated policies could shift to covering those options, which would potentially reduce overall costs. Additionally, if in the future more DMHC-regulated Medi-Cal plans began including an outpatient pharmacy benefit, that cost increase would include compliance with AB 2467.

The long-term public health impacts of AB 2467 are expected to be similar to those described in the short-term impact section. Most bill-specified drug categories (where most prescriptions are concentrated) are already covered at baseline. Therefore, CHBRP anticipates that a limited number of women (especially those with hormone-sensitive cancer experience) will continue to access the newly covered categories.